Remarks

Claims 23-25 and 42-44 are pending and under consideration in the application. Applicants thank the Examiner for the withdrawal of certain objections and rejections.

Rejection of Claims 23-25 and 42-44 Under 35 U.S.C. § 103

The rejection of claims 23-25, 42, and 43 under 35 U.S.C. § 103(a) has been maintained as allegedly being unpatentable over Cole et al. (Clinical Chemistry Feb 2001; hereinafter Cole) in view of O'Connor et al. (U.S. 6,500,627; hereinafter O'Connor) in light of Birken et al. (2001; hereinafter Birken 2001) in view of Hochstrasser et al. (US 2003/0157580; hereinafter Hochstrasser) and Birken et al. (US 6,521,416; hereinafter Birken '416). Claim 44 has been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Cole in view of O'Connor in light of Birken 2001 in view of Hochstrasser and Birken '416, and further in view of Campbell et al. (US 4,946,958; hereinafter Campbell).

According to the Examiner, it would have been obvious to one of skill in the art to incorporate antibodies and labels as taught by O'Connor et al. into the method of diagnosing as taught by Cole et al.

The teachings of the references have been characterized in Applicant's previous response. Applicant traverses the rejection for the following reasons.

Applicant's claims are directed to a diagnostic method that uses two different antibodies, "a first antibody that specifically binds hyperglycosylated human chorionic gonadotropin" and "a different second antibody that specifically binds human chorionic gonadotropin".

As set forth in Example 3 of the instant application (page 27 of the specification as originally filed), the "combo" assay using an antibody to hyperglosylated hCG ("B152") and an antibody to free beta hCG ("827") yields unexpected results, in that the combo assay provided about "6 to 12 times greater sensitivity" than the assay using only the B152 antibody (the B152-B207 assay; B207 was the antibody used for detection). Additionally, as stated in Cole (page 314, second and third full paragraphs), using hCG to diagnose choriocarcinoma gave a high incidence of false positive results (which can lead to unnecessary treatment, including surgery and chemotherapy).

Applicant submits that it would not have been obvious to one of skill in the art at the time the invention was made to use two different antibodies, one for hyperglycosylated hCG and one for hCG, because one of skill in the art could not have expected that using an antibody to hCG would increase the sensitivity of an assay for hyperglycosylated hCG. Furthermore, there is no teaching or suggestion in any of the cited references that the use of two such antibodies together in the same assay would be advantageous in the detection of trophoblast disease.

Applicant submits that because claim 44 depends from independent claim 23, and because claim 23 is unobvious, as discussed above, claim 44 is similarly unobvious over the cite references.

In view of the above, applicant submits that the present claims are unobvious from and patentable over the cited references, taken alone or in any combination, and respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. § 103.

Conclusion

In conclusion, applicant submits that each of the outstanding rejections have been overcome, and that the present claims are in condition for allowance, notice of which is respectfully requested. If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicant's undersigned representative invites the Examiner to telephone him at the number provided below.

Respectfully submitted,

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